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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/225,233	01/04/1999	KEITH HENRY STOCKMAN CAMPBELL	112800.401	2711

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EXAMINER	
CROUCH, DEBORAH	
ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 12/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	Application No. 09/225,233	Applicant(s) CAMPBELL ET AL.	
	Examiner Deborah Crouch, Ph.D.	Art Unit 1632	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 16 November 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *146-163*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☒ Other: See Continuation Sheet.

Deborah Crouch

Deborah Crouch, Ph.D.
Primary Examiner
Art Unit: 1632

Continuation of 11. does NOT place the application in condition for allowance because: : With regard to the rejection under 35 U.S.C. § 101, that applicant's clones are non-statutory subject matter, applicant argues the clones are replicas or copies of pre-existing mammals. The clone requires the "hand of man" in order to exist and thus is statutory subject matter. Applicant further argues the clone is not the same mammal because the clones exists at a different space and time than the previously known mammal. Further, applicant argues that the clone will have phenotypic and behavioral differences from the pre-existing mammal. These arguments are not persausive. A patentable distinct cannot be discserned between the claimed clones and the mammals from which they were cloned. Any phenotypic or behavioral differences are not disclosed in the specification. The specification contains no disclosure that the clone is different from the nuclear donor mammal.

With regard to the rejection under 35 U.S.C. § 112, enablement, applicant argues with regard to cloning mice, their specification discloses a prolonged interval between nuclear injection and oocyte activation (pages 12-13). This not persuasive because the disclosure is the time of activation is species dependent and for cows the interval is 6-20 hours. However, there is no disclosure that would guide the artisan to specific interval used by Wakayama. 1-6 hrs. Applicant aruges, with regard to rabbits, that Chesne used asynchronous transfer with in vitro manipulated rabbit embryos, and this was known in the art at the time of filing (Landa, 1981 and Al-Hasani, 1986). This is not persausive because there is no guidance in the specfication to use asynchronous rabbit (or anyother species) embryos to produce cloned rabbits by nuclear transfer. Landa and Al-Hasani used asynchronous embryo that had been cultured in vitro prior to implantation into a female rabbit, and not embryos b produced by nuclear transfer. With regard to horses, applicant argues Galli cites Lazari (2002) which teaches activation studies in horses with a protein synthesis inhibitor and a protein phosphorylation inhibitor. Applicant argues that it was known in the art at the time of filing to inhibit protein synthesis and protein phosphorylation sequentially (Susko-Parrish). This is not persausive because Galli found that horse nulcear transfer methods worked when both protein synthesis inhibition and protein phosphoryation inhibition were performed at thet same time. This simultaneous inhibition is not taught in the specfication or Susko-Parrish. With regard to rats, applicant argues the specification teaches reconstructing an embryo using a non-activated MII oocyte. Applicant argues that Zhous' successful cloning of rats was performed according to their techniques. This argument is not persausvie. The specification at page 4 states MII arrested oocytes have to also be incubated to maintain ploidy of the transferred nucleus, which on page 14 is to incubate in the presence to nocodozole. More that just maintaining oocytes in a non-activated state is disclosed.

With regard to the rejections under 35 U.S.C. § 102/103, applicant argues that the clones are replicas to prior existing, non-embryonic donor mammals, and until their invention no such replicas existed. Applicant argues that the clone and the nucleus donor mammal will have phenotypic and behavioral differences, and thus are not identical. Applicant argues the clone and the nucleus donor mammal do not exist at a different space and time. This argument is not persausve. First, the clone and the donor can exist in the same space and time, if they overlap. There is no requirement in the specfication or the claims that the donor mammal be dead when the clone is made. Further, there is no disclosure in the specfication that the clone will have phenotypic or behavioral differences from the donor mammal, or that any such differences produce a mammal with new and novel/non-obvious patentable distinction. Applicant argues that prior to their invention no mammal existed that obtained its entire set of chromozomes from one parent. This argument is not persausive. If the clone contains the same set of chromomes as contained in another mammal, then, the clone and the mammal are the same, and any characteritics that are different cannot render the clone patentable over the mammal. .

Continuation of 13. Other: Applicant's agreement to filed terminal disclaimers in compliance with 37 CFR 1.321(c) over US Patents 6525243; 6147276,6252133 is noted. This rejection, however, is maintained for reasons of record as the TD's have not yet been filed and approved. .